UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA *et al., ex rel.* DAVID KESTER, Plaintiffs, - v - NOVARTIS PHARMACEUTICALS CORPORATION, *et al.*, Defendants.	:	11 Civ. 8196 (CM)(JMF) ECF Case

MEMORANDUM OF LAW OF THE UNITED STATES IN OPPOSITION TO NOVARTIS'S MOTION TO DISMISS

PREET BHARARA
United States Attorney for the Southern
District of New York
86 Chambers Street, 3rd Floor
New York, New York, 10007
Telephone: (212) 637-2734/2714/2722/2746

Of Counsel:

LI YU
REBECCA C. MARTIN
ROBERT WILLIAM YALEN
TARA M. LaMORTE
Assistant United States Attorneys

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In accordance with the Court's May 29th Memorandum Opinion and Order ("*Novartis I*" or "May 29 Decision"), [Dkt. 192], the United States ("Government"), by its attorney, Preet Bharara, United States Attorney for the Southern District of New York, respectfully submits this memorandum of law in response to Novartis's renewed motion to dismiss ("NPC Br."). [Dkt. 203]. For the reasons set forth below, Novartis's motion should be denied.

PRELIMINARY STATEMENT

The Court invited the parties to address whether, as Novartis argued, a 2010 amendment to the Anti-Kickback Statute ("AKS"), codified at 42 U.S.C. § 1320a-7b(g),[1] injects a "but for" cause requirement into the standard of falsity under the False Claims Act, *i.e.*, whether "only claims directly caused by [] an illegal recommendation are inconsistent with the certification of AKS compliance" and thus false. *Novartis I* at 42. As in its initial papers, Novartis again posits that, under the AKS amendment, the Government must plead "a 'but for' nexus between the alleged kickback scheme and [a] prescribing decision" to show legal falsity. NPC Br. at 3.

Novartis's construction cannot be squared with the text, context, or legislative history of the AKS amendment. In enacting that amendment, Congress intended to confirm that all claims tainted by kickbacks are "false" under the FCA and to correct a court decision erroneously holding that a claim for a service induced by a kickback cannot be false if it is submitted by an innocent party. While several courts have viewed the AKS amendment as a clarification confirming that kickback-tainted claims are false, *see, e.g.*, *U.S. ex rel. Westmoreland v. Amgen, Inc.*, 812 F. Supp. 2d 39, 52-53 (D. Mass. 2011), no court has interpreted it as inserting a separate, but for causation requirement into the FCA's falsity standard. Indeed, it would

[1] This section provides "a claim that includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim for purposes of [the False Claims Act]."

frustrate Congress's purpose to read the AKS amendment, as Novartis suggests, as a means to curtail the Government's remedies by altering the standard of falsity under the FCA.

Novartis does not, and cannot, claim that a "but for causation" requirement can be found in the plain language of the AKS amendment; instead, it purports to derive that requirement from context, the purposes of the FCA and the AKS, and public policy. *See* NPC Br. at 12-22. Novartis bases that erroneous conclusion on a set of glaring omissions and inaccuracies. First, it fails to acknowledge a key context for the AKS amendment — that courts had previously rejected the "but for cause" requirement it proposes here. *See infra* at 7-8. Next, in its statutory purpose analysis, Novartis does not recognize the FCA's broad remedial purpose and also wrongly suggests that the AKS is concerned only with doctors' judgment. *See infra* at __. Finally, Novartis also misreads the 2010 AKS amendment itself by incorrectly equating the statutory term "items or services" with "prescriptions," rather than the actual drug shipments dispensed. *See infra* at 3.

Novartis needs to present those omissions and inaccuracies because its legal arguments lack merit. The AKS amendment – interpreted in light of its text, context, and legislative history – simply confirms that "[c]laims tainted by kickbacks are 'false or fraudulent' claims within the meaning of the FCA," *Hendricks v. Lincare Inc.*, Civ. A 07-383, 2014 WL 1225660, at *4 (E.D. Pa. Mar. 25, 2014), and does not curtail the Government's remedies under the FCA by injecting a "but for cause" element into the falsity analysis. *See infra* Point I.A.

Further, Novartis's statutory purpose argument also fails once the "but for cause" requirement is considered against the actual purposes of the AKS and the FCA. Congress enacted the AKS to proscribe fraud and abuse in the healthcare system by all actors, including pharmacies. The FCA, in turn, provides the Government with civil remedies for "all fraudulent attempts to cause the Government to pay out sums of money," *United States v. Neifert-White,*

Co., 390 U.S. 228, 233 (1968), including claims tainted by kickback violations. Here, there already is a causation element to the Government's FCA claims against Novartis, to inject a separate "but for cause" requirement into the falsity analysis would frustrate the statute's remedial purpose. *See infra* Point I.B.

Under the correct interpretation of the FCA and AKS, the Government's actual allegations – instead of the skewed version Novartis presents, *see infra* at 4-6 – plainly show that Novartis's AKS violations "tainted" the Exjade and Myfortic claims cited in the complaint. As to Exjade, the claims were for drugs shipped to patients that Novartis referred to BioScrip as inducements for promoting Exjade refills; and, as to Myfortic, the claims were tainted by how Novartis structured the kickbacks, *i.e.*, using market share rebates to induce pharmacies not only to switch patients to Myfortic, but also to keep patients on Myfortic. *See infra* at Point II.A. Further, as the Court noted in its May 29 Decision, the Government also alleges that pharmacies receiving kickbacks from Novartis violated their express certifications to comply with AKS. *See Novartis I* at 35-36. This provides another basis for falsity, and Novartis has opted *not* to address the false express certifications. *See infra* at Point II.B

Finally, insofar as Novartis asks the Court to impose a "but for" requirement based on its perception that the Government's theory is "overbroad," *see* NPC Br. at 21-22, this argument is meritless. If anything, Novartis's hypotheticals – which ignore the existence of express certifications and fail to include basic facts like how the defendants structured their kickback relationships – show injecting a rigid "but for causation" requirement would contravene the FCA's basic remedial purpose. *See infra* Point III.

NOVARTIS'S MISLEADING SUMMARY OF THE GOVERNMENT'S ALLEGATIONS

Novartis distorts the Government's amended complaint by misrepresenting and selectively omitting many of its key allegations. First, Novartis absurdly suggests that the "items or services" paid for by the Government were "prescriptions," instead of drug shipments. Second, Novartis effectively ignores the allegations that Exjade patient referrals were the primary form of inducement that Novartis offered to BioScrip. Finally, Novartis fails to acknowledge the allegations that it structured the Myfortic kickbacks to induce pharmacies both to switch patients to Myfortic and to keep patients on Myfortic. Below, we briefly contrast Novartis's distortions with what the Government in fact alleged.

A. The "Items or Services" That the Government Paid for Were the Exjade and Myfortic Shipments Dispensed by Pharmacies, Not Prescriptions

Novartis repeatedly asserts the only "items or services" for which pharmacies claimed Medicare and Medicaid reimbursement "are prescriptions for Exjade and Myfortic." NPC Br. at 14 ("[t]he 'items and services' included in the claims for reimbursement at issue (42 U.S.C. § 1320a-7b(g)) are prescriptions for Exjade and Myfortic"); *see also id*. at 2.

This claim is patently false and a mischaracterization of the Government's allegations — pharmacies bill Medicare and Medicaid for drugs they dispense, not for prescriptions issued by another party.[2] The amended complaint does not allege pharmacies like BioScrip and Bryant's submitted claims for "*prescriptions* for Exjade and Myfortic;" instead, it alleges that they billed the Government for the Exjade or Myfortic *shipments* they dispensed to patients. *See, e.g.*, US Am. Compl. at ¶ 227 ("from February 2007 to May 2012, BioScrip submitted claims to Medicare Part D and Medicaid seeking reimbursement for the Exjade shipments it dispensed.");

[2] Novartis appears to misleadingly equate "items or services" to "prescriptions" because it wants to focus solely on the doctors writing prescriptions, rather than the pharmacies dispensing the drugs and billing the Government for those drug shipments. But, as discussed below, the AKS is *not* just about giving improper inducement to doctors. *See infra* at 16.

id. at ¶ 82 ("Any Medicare or Medicaid claim submitted by Bryant for Myfortic dispensed in connection with its illegal arrangement with Novartis was false ...").

B. **Patient Referrals Were the Main Form of Inducement in the Exjade Scheme**

Novartis's brief pointedly ignores the Government's allegations that Novartis leveraged its control over Exjade patient referrals to induce BioScrip to promote the drug directly to patients. After making a passing reference to these allegations, *see* NPC Br. at 5, Novartis goes on to suggest that the only inducement it is alleged to have offered BioScrip was limited to "NPC's discounts" or "supposed kickback payments." *See id*. at 5, 14.

Yet, even a cursory reading of the Government's amended complaint makes clear that patient referrals, rather than discounts, were the main inducement used in the Exjade kickback scheme. Specifically, the Government alleges that the scheme began when Novartis conditioned "BioScrip's access to Exjade patient referrals" on BioScrip agreeing to "initiate an intensive effort to call Exjade patients to recommend refills and to get patients who stopped ordering Exjade to restart," *see* US Am. Compl. at ¶¶ 145, 177-85; next, Novartis used the prospect of getting more patient referrals to prompt BioScrip to continue promoting Exjade for Novartis under the guise of clinical counseling and education, *id*. at ¶¶ 177-85; and, finally, Novartis reduced the flow of patient referrals to BioScrip in early 2011 as a "warning" when Novartis perceived BioScrip's efforts to promote Exjade to be flagging.[3] *See id*. at ¶¶ 219-222.

C. **Novartis Used Market Share Rebates to Induce Pharmacies Both to Move Patients to Myfortic and to Keep Patients on Myfortic**

With regard to Myfortic, Novartis fails to acknowledge or address the Government's allegations that Novartis typically structured the inducements to pharmacies, like Bryant's and

[3] Indeed, the Government also emphasized that Exjade patient referrals were the principal form of inducement used by Novartis in the Exjade scheme in its March 21, 2014 letter-brief. *See id*. at 3-5 [Dkt. 163].

Kilgore, as "performance rebates" tied to Myfortic's market share among the pharmacies' transplant patients. As explained in the Government's amended complaint, Novartis's basic objective for the Myfortic kickback scheme was not just to gain a one-time benefit, but to guarantee a steady stream of sales throughout the lives of the transplant patients served by the pharmacies taking part in the scheme. *See* US Am. Compl. at ¶¶ 69-70, 125-27.

To ensure that it would reap ongoing sales from its kickback relationship with the pharmacies, Novartis structured the kickbacks as "market share rebates" so that, once a pharmacy agreed to recommend Myfortic in exchange for kickbacks, the pharmacy's economic interests were tied to those of Novartis. As Novartis records show, the market share rebate arrangements gave the pharmacies a financial incentive to "control [Myfortic] market share" by keeping patients, including patients who may not have been switched as an initial matter, on the drug. *Id.* at ¶¶ 74, 125. Thus, when generic competitors to Myfortic became available, the owner of Bryant's Pharmacy "argued" against the less expensive generics so that he could continue receiving getting rebates. *Id.* at ¶¶ 76-78. Further, Novartis also recalibrated the market share rebates when it was necessary to ensure that pharmacies like Bryant's would keep patients on Myfortic. When Bryant's owner saw that his existing kickback arrangement with Novartis was no longer financially satisfactory, the owner told Novartis he would start to "convert [his] Myfortic patients to generic[s]." *Id.* at ¶ 78. Novartis then agreed almost immediately to modify the terms of that arrangement to keep rebates flowing to Bryant's so that the pharmacy would remain Novartis's "staunch ally," *i.e.*, keep patients on Myfortic. *Id.* at ¶¶ 79-80.

ARGUMENT

POINT I

THE 2010 AKS AMENDMENT DOES NOT INJECT A "BUT FOR CAUSE" REQUIREMENT INTO THE FALSITY STANDARD IN CASES BASED ON KICKBACK VIOLATIONS

A. The 2010 AKS Amendment Confirms Claims Tainted by Kickbacks Are False, and Does Not Inject a "But for Cause" Requirement Into the Falsity Analysis

The 2010 AKS amendment provides that "a claim that includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim for purposes of [the False Claims Act]." 42 U.S.C. § 1320a-7b(g). As courts have consistently recognized, Congress enacted this provision to (i) confirm its agreement with the principle, which had been recognized by most courts, that claims tainted by kickbacks are false under the FCA, and (ii) correct an erroneous district court decision holding that a claim for an item or service tainted by a kickback cannot be false if the claim is submitted by an innocent party. *See U.S. ex rel. Westmoreland v. Amgen, Inc.*, 812 F. Supp. 2d 39, 52-53 (D. Mass. 2011) (the 2010 AKS amendment "was intended . . . to clarify the reach of the Anti–Kickback Statute, which had been called into question by recent litigation"); *U.S. ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 312 n. 19 (3rd Cir. 2011) (the 2010 AKS amendment was a clarification); *Parikh*, 977 F. Supp. 2d at 664 n.3 (same); *see also Lincare*, 2014 WL 1225660, at *4 (the amendment shows "[c]laims tainted by kickbacks are 'false or fraudulent' claims within the meaning of the FCA").

Nonetheless, Novartis claims that the statutory term "resulting from" must be read to indicate that Congress sought to modify the elements of the FCA by tacking on a separate, "but for cause" requirement onto the falsity standard in the kickback context. Novartis cannot derive its "but for cause" requirement from the plain language of the statute, but instead claims that the requirement should be inferred from the statutory context. However, the context and legislative history of the 2010 AKS amendment indicate otherwise.

Courts "assume that, when Congress enacts statutes, it is aware of relevant judicial precedent." *Merck & Co., Inc. v. Reynolds*, 559 U.S. 633, 648 (2010). Thus, how courts had analyzed falsity in FCA cases involving kickbacks was a key context for the AKS amendment. Prior to 2010, several courts had addressed whether, to establish falsity in a FCA case involving kickbacks, it is necessary to show – as Novartis suggests here – that kickbacks caused the use of a drug or service that was not medically necessary. In those cases, courts routinely rejected such a requirement. *See, e.g.*, *United States v. Rogan*, 517 F.3d 449, 453 (7th Cir. 2008); *U.S. ex rel. Thompson v. Columbia/HCA Healthcare Corp*., 20 F. Supp. 2d 1017, 1047 (S.D. Tex. 1998); *U.S. ex rel. Pogue v. Am. Healthcorp, Inc*., 914 F. Supp. 1507 (M.D. Tenn. 1996).

As Judge Easterbrook recognized in *Rogan*, the Government conditions payment on compliance with the AKS. 517 F.3d at 453. Thus, it does not matter for purposes of the FCA whether "the patients had gone elsewhere, the United States would have paid for their care" or "perhaps the patients, or a private insurer, would have paid for care at [the defendant] had it refrained from billing the United States." *Id*. In other words, a claim triggers liability under the FCA if it is linked to or tainted by a kickback violation, not just when that violation results in unnecessary medical treatment or achieves "success" for the participants in the scheme. *Cf.* H.R. Rep. 95-92 (1977), 95th Cong., 1st Sess. at 47, *reprinted in* 1977 U.S.C.C.A.N. 3039, 3050 (in enacting the AKS, Congress recognized that, because "the medical needs of a particular patient can be highly judgmental," "it is difficult" to identify or prove "excessive services").

Thus, insofar as Novartis suggests that the 2010 AKS amendment injects a "but for cause" requirement into the falsity analysis, it is asking the Court to disagree with several other courts and conclude that Congress intended to overrule the pre-existing judicial decisions and curtail the Government's remedies under the FCA for AKS violations. Legislative history of the AKS amendment, however, shows that Congress intended "to strengthen," rather than to curtail,

"fraud enforcement." *See* 155 Cong. Rec. S10852, 10854, 2009 WL 3460582, at *S10854. Further, the legislative history also makes clear that Congress explicitly stated its purpose when it intended for the legislation to counteract a judicial decision, like the district court decision in *U.S. ex rel. Thomas v. Bailey*, 2008 WL 4853630 (E.D. Ark. Nov. 6, 2008). *See id*. at *S10853 (Senator Kaufman stating that the amendment was intended to "remed[y] the problem" created by a court decision insulating kickback recipient from liability under the FCA).

In *Thomas*, the *qui tam* relator alleged that kickbacks accepted by a doctor in return for using a particular company's products during surgeries tainted the claims for those surgeries submitted by hospitals. 2008 WL 4853630, at *8. But the district court held that such claims were not false under the FCA, even though they included products tainted by kickbacks, because the hospital did not certify as to the physician's compliance with the AKS. *Id*. at *12-13. As sponsors of the AKS amendment explained, that statute was enacted in part to subject "all payments that stem from an illegal kickback [] to the False Claims Act" and, thus prevent the "laundering" of kickback-tainted claims through third-parties as in *Thomas*. 155 Cong. Rec. S10853, 2009 WL 3460582, at *S10853; *see also Westmoreland*, 812 F. Supp. 2d 39, 52-53. In short, the legislative history establishes that Congress did not intend to curtail the reach of the FCA by injecting a separate causation requirement into the falsity analysis and, in the process, overrule the existing precedents *sub silentio*.

The text of the 2010 AKS amendment reflects the Congressional purpose evidenced by the statutory context and legislative history.[4] Specifically, the statutory term "resulting from," which characterizes the relationship between a kickback violation and an item or service, incorporates the concept from decisions like *Rogan* that what is being claimed from the

[4] Courts must "interpret the relevant words not in a vacuum, but with reference to the statutory context, structure, history, and purpose." *Abramski v. United States*, 134 S. Ct. 2259, 2267 (June 16, 2014).

Government needs to be linked to or tainted by the kickbacks. By using that phrase, the statute encompasses scenarios where the connection between the AKS violation and the item or service being claimed may be temporally distant and where an item or service tainted directly by a kickback may be bundled into a claim for multiple items and services.

In other words, "resulting from" signals nothing more than that the taint from kickback violation remains with an item or service irrespective of when a claim for that item or servie is made, which entity submits the claim, or what payment mechanism the Government uses to reimburse the claim, and it does not encompass the "but for causation" requirement suggested by Novartis. *See United State v. Shellef*, 718 F.3d 94, 107 (2d Cir. 2013) (construing the term "resulting from" in the Speedy Trial Act as not "requiring 'but for' causation"). Such flexibility is consistent with Congress's purpose because, as its text shows, the AKS is meant to prevent fraud and abuse on federal healthcare programs by targeting many variations of kickback relationships. *See* 42 U.S.C. § 1320-7b(b)(2) (proscribing the solicitation, receipt, offer, and payment of "any remuneration ... directly or indirectly, overly or covertly, in cash or in kind [] in return for" referrals, purchases, leases, orders, and "arranging for or recommending" any purchase, lease, order of "any good, facility, service, or item").[5]

By contrast, to adopt Novartis's suggestion and read the 2010 AKS amendment as inserting a "but for cause" requirement into the falsity standard would undermine the FCA's broad remedial purpose. *See Neifert-White Co.*, 390 U.S. at 233 (the FCA is a "remedial statute"); *U.S. ex rel. Feldman v. Van Gorp*, 697 F.3d 78, 95 (2d Cir. 2012). Indeed, where, as

[5] This also accords with dictionary definitions of "result," which denote a temporal sequence (an event resulting from an earlier action) and an "effect" from the earlier action on the resulting event. *See, The Oxford English Dictionary* (2d ed. 1989) at 761 (defining result as "to arise as a consequence, effect, or conclusion from some action"); *Merriam-Webster's Dictionary* (10th Ed. 1999) at 992-93 (defining result as "to proceed or arise as a consequence, effect, or conclusion"); *Webster's Third New International Dictionary* (2002) at 1925 (defining result as "to proceed, spring, or arise as a consequence, effect, or conclusion" or "to terminate or end").

here, "resulting from" or a similar term is used in a statutory provision with a remedial purpose, courts have rejected imposing a rigid, "but for cause" requirement. *See, e.g.*, *Paroline v. United States*, 134 S. Ct. 1710, 1727 (Apr. 23, 2014) (it "would be unacceptable to adopt a causal standard so strict that it would undermine congressional intent where neither the plain text of the statute nor legal tradition demands such an approach"); *Nat'l Ass'n of Mfrs. v. U.S. Dep't of Interior*, 134 F.3d 1095, 1103 (D.C. Cir. 1998) (rejecting interpretation of the term "resulting from" in CERCLA as imposing "a burden to demonstrate that a particular release in fact caused injury to a specific natural resource").[6]

B. Injecting a "But for Cause" Requirement into the FCA's Falsity Standard Would Contravene the Purposes of the AKS and the FCA

Novartis also asks the Court to add a "but for cause" requirement to the "legal falsity" because, it claims this is "consistent with the purpose of the AKS and the FCA." NPC Br. at 16. The Court should reject this entreaty because Novartis bases its contention on a distortion of the actual purposes of the two statutes — the AKS is not, as Novartis suggests, concerned only with whether *doctors* exercise independent clinical judgment; and, while the FCA originated as a Civil War-era law designed to combat fraud involving "inflated invoices and faulty goods," Congressional amendments and judicial decisions have long since broadened the FCA's remedial reach to "all fraudulent attempts to cause the Government to pay out sums of money." *Neifert-White Co.*, 390 U.S. at 233.

First, the AKS's text, as well as agency guidance and court decisions applying the statute, all make clear it proscribes the use of kickbacks to improperly influence *all* the actors involved in the provision of healthcare services – hospitals, pharmacies, formulary committees, pharmacy

[6] In certain criminal cases where the term "results from" is used to define an element of an offense for purposes of determining the sentence, courts have interpreted it as "but for causation." *See, e.g.*, *Burrage v. United States*, 134 S. Ct. 881, 887-89 (Jan. 23, 2014); *United States v. Hatfield*, 591 F.3d 945, 948 (7th Cir. 2010).

benefit managers, as well as doctors. To begin with, the AKS expressly proscribes "*whoever* knowingly and willfully solicits or receives any remuneration ... in return for ... referring an individual to a person for the furnishing ... of any item or service" or for "purchasing, leasing, ordering, or arranging for or recommending" the purchase or order of "any good, facility, service, or item" covered by the Government. 42 U.S.C. § 1320a-7b(b)(1) (emphasis added); *see also United States v. Vernon*, 723 F. 3d 1234, 1254 (11th Cir. 2013) (by its "plain language," the AKS "is not limited to payments to physicians who prescribe medication"). This broad statutory prohibition reflects the basic principle that federal healthcare programs, including Medicare and Medicaid, must function free of the insidious effects of kickbacks from any quarter. *See United States v. Ruttenberg*, 625 F.2d 173, 177 n.9 (7th Cir. 1980) (recognizing that "kickback schemes can freeze competing suppliers from the system, can mask the possibility of government price reductions, can misdirect program funds").

Further, as the Court noted, HHS-OIG, the agency with AKS expertise, has long given notice that the AKS bars offering remuneration to induce pharmacies to perform "marketing tasks" targeting patients as well as physicians. *Novartis I* at 33. Finally, courts have routinely held that the AKS is violated if kickbacks are offered to improperly influence the decisions of actors other than doctors, including pharmacies. *See, e.g., McNutt ex rel. U.S. v. Haleyville Med. Supplies, Inc.*, 423 F.3d 1256, 1258 (11th Cir. 2005) (affirming denial of motion to dismiss FCA claims based kickbacks paid by a medical service firm to a pharmacy for referrals); *United States v. Polin*, 194 F.3d 863, 866-67 (7th Cir. 1999) (affirming criminal convictions of physician and nurse for offering kickbacks to a device sales representative in return for referrals of patients on Medicare); *In re Pharm. Indu. Avg. Wholesale Price Litig.*, 491 F. Supp. 2d 12 (D. Mass. 2007) (upholding claims alleging kickbacks from drug-maker to pharmacies, in the form of "marketing the spread" between AWP and acquisition cost of drugs, in return for purchasing drugs); *U.S. ex*

rel. Lisitza v. Johnson & Johnson, 765 F. Supp. 2d 112 (D. Mass. 2011) (upholding claims alleging kickbacks from drug-maker to pharmacy in return for recommending its drugs to long-term care facilities).

Novartis likewise fails to explain that, since its original enactment, the FCA has been amended several times, including in 1986, when "Congress substantially amended the FCA with the intent of encouraging [FCA] actions." *Mortgages, Inc. v. United States Dist. Court*, 934 F.2d 209, 212 (9th Cir. 1991). The purpose of the 1986 amendment was to ensure the FCA could achieve its intended remedial purpose – "to reach all types of fraud, without qualification, that may result in financial loss to the Government." S. Rep. 99-345, at 19 ("strongly endors[ing]" this articulation of the FCA's purpose from *Neifert-White*, 390 U.S. at 28).

Novartis's view is that kickbacks tied to drug shipments do not taint those shipments except where the doctor writing a prescription were influenced to change his or her opinion, but this view simply cannot be squared with the purposes of the AKS and the FCA. The Government conditions payment on compliance with the AKS, *Rogan*, 517 F.3d at 453; and the AKS is concerned with conduct, not the success or outcome of such conduct. *See Novartis I* at 34; *see also* H.R. Rep. 95-393 at 47 (in enacting the AKS, Congress did not contemplate requiring proof that unnecessary good or services were used because "the medical needs of a particular patient can be highly judgmental"). Thus, there is nothing inconsistent with the purpose of the FCA or the AKS for a claim connected to a kickback scheme to be deemed false. In anything, this follows from the principle Novartis itself derives from *U.S. ex rel. Colucci v. Beth Israel Med. Ctr.* — "a claim is false or fraudulent if it is aimed at extracting money the Government otherwise would not have paid." NPC Br. at 17 (citing *Colucci*, 785 F. Supp. 2d 303, 310 (S.D.N.Y. 2011)). Indeed, Novartis's own compliance policy recognize that pharmacy staff are healthcare professionals and that Novartis should not interfere with a pharmacy's

independence by offering anything "intended to have an inappropriate influence on [its] decision to *dispense* ... products." US Am. Compl. at ¶ 50 (emphasis added).

Finally, in cases like this, causation already is an element of the Government's claims against Novartis. As the Court noted, the Government needs to prove that Novartis caused false claims to be presented to Medicare and Medicaid or caused false statements or records to be used in connection with false claims. *Novartis I* at 15. To inject a separate "but for causation" requirement into the *falsity* element would undermine and frustrate the FCA's remedial purpose.

POINT II

THE AMENDED COMPLAINT HAS SUFFICIENTLY ALLEGED THAT THE CLAIMS CITED BY THE GOVERNMENT WERE TAINTED BY NOVARTIS'S AKS VIOLATIONS AND, THUS, FALSE

A. The Government Has Amply Pled That Novartis's AKS Violations Tainted the Exjade and Myfortic Claims Cited in the Complaint

The "item[s]" for which pharmacies billed Medicare and Medicaid reimbursements in this case were the Exjade and Myfortic shipments (rather than prescriptions) dispensed to patients. *See supra* at 4. Further, as the Court recognized, "it is the kickback arrangement itself that constitutes the AKS violation, not the success of the arrangement." *Novartis I* at 34.

Thus, claims are false for purposes of FCA to the extent they include Exjade and Myfortic shipments connected to or tainted by Novartis's offer of kickbacks to the pharmacies in the forms of patient referrals and rebates. *See* 42 U.S.C. § 1320a-7b(g); *see also Lincare*, 2014 WL 1225660, at *4. Here, the Government's allegations – considered in their entirety rather than the misleading version presented by Novartis, *see supra* at 4-6 – show that the requisite connection or taint exists between the kickbacks offered by Novartis and the Exjade and Myfortic shipments giving rise to the claims cited in the complaint.

First, in the Exjade scheme, Novartis, which controlled patient referrals through its EPASS network, purposely linked BioScrip's access to the Exjade patients to whether BioScrip

would recommend Exjade refills to patients and get patients who had stopped taking the drug to restart. *See supra* at 5. Specifically, Novartis told BioScrip in February 2007 that failure to increase its refill levels could result in its ejection from EPASS and the loss of the Exjade patients. *See* US Am. Compl. at ¶ 177. Further, Novartis also offered BioScrip rebates payable based on each Exjade shipment. *See id*. at ¶¶ 150, 165, 189.

Under these facts, Novartis's AKS violation – giving Exjade patient referrals and discounts to induce BioScrip to recommend refills – is directly connected to the Exjade shipments dispensed by BioScrip during the course of the scheme. First, without the Exjade patients it had by virtue of being allowed to remain in the EPASS network, BioScrip could not have shipped any Exjade or made any claims to Medicare or Medicaid for such shipments. Second, by tying the payments it offered BioScrip to each individual shipment, Novartis made each shipment a part of the very structure of the kickback scheme. Accordingly, all the Exjade claims cited in the Government's amended complaint, *see* US Am. Compl. at ¶ 229, were "tainted" by kickbacks. *See Rogan*, 517 F.3d at 453 (all Medicaid claims connected to a kickback scheme involving patient referrals are false under the FCA); *U.S. ex rel. Freedman v. Suarez-Hoyos*, 8:04-CV-933-T-24 EAJ, 2012 WL 4344199, at *4 (M.D. Fla., Sept. 21, 2012) (treating claims for patients referred as part of a kickback scheme as "tainted" and thus false); *U.S. ex rel. Fry v. Health Alliance of Greater Cincinnati*, 2008 WL 5282139, at *12 (same). Those claims, thus, are false under the FCA.

Second, in the case of Myfortic, Novartis offered kickbacks to the pharmacies in the form of market share rebates to give the pharmacies an inducement not only to switch patients to Myfortic, but also to "control market share" by keeping patients on Myfortic. *See supra* at 6.[7]

[7] Novartis did not offer a market share rebate to the outpatient pharmacy at Baylor Hospital, which only served patients for one year post-transplant. *See* US Am. Compl. at ¶¶ 83-

Indeed, internal discussions among Novartis managers show that Novartis saw the market share rebates as a means to turn the pharmacies into "staunch all[ies]" in terms of preventing patients from switching from Myfortic to a competitor drug. *See* US Am. Compl. at ¶¶ 76-80, 102-06. By purposely structuring the Myfortic kickbacks this way, Novartis not only made each shipment dispensed by the pharmacies an integral part of the scheme, it also tried to influence the pharmacies' clinical judgment with respect to all their Myfortic patients, irrespective of whether the patients had been switched to Myfortic. Thus, Novartis's kickback scheme "tainted" all the Myfortic shipments dispensed by the pharmacies during the scheme, *i.e.*, the shipments included in the claims in the amended complaint. *See Westmoreland*, 812 F. Supp. 2d at 69. Thus, those claims also are false for purposes of the FCA.

B. **The Pharmacies' Express Certifications of AKS Compliance Also Provide A Basis for Falsity**

As the Court noted, the Government also bases falsity on the allegations that Novartis caused pharmacies to contravene their express certifications and representations to Medicare and Medicaid to comply with the AKS. *See Novartis I* at 35-36. Although the Court invited briefing on whether the 2010 AKS amendment injects a "but for cause" requirements for claims submitted under false express certifications, *id.* at 40-41, Novartis's brief does not addresses this issue. Further, while Novartis, in a footnote, *see* NPC Br. at 15 n .3, purports to rely on arguments from CVS and Accredo against relator's claims, neither CVS's nor Accredo's briefs discuss how the AKS amendment affects claims submitted under false express certifications.

By failing to address this issue, Novartis has waived any argument against the Government's theory falsity insofar as it is based on the false express certifications or

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91. But, because Baylor pharmacy "committed" to achieve "100% conversion" of its patients to Myfortic in exchange for the kickbacks from Novartis, *id.* at ¶ 86, the Court can infer that all or substantially all of Baylor's Myfortic claims cited in the complaint were the result of its unlawful conversion agreement with Novartis.

representations made by the pharmacies. *See Poupore v. Astrue*, 566 F.3d 303, 306 (2d Cir. 2009) (argument not raised in an opening brief is waived); *Kingsway Fin. Servs., Inc. v. Pricewaterhouse-Coopers*, 03 Civ. 5560 (RMB), 2008 WL 5423316 (S.D.N.Y. Dec. 31, 2008) (same). Further, Novartis's silence is telling — the pharmacies' express certifications were conditions of payment by the federal programs like Medicare Part B and Part D and Medicaid, and claims submitted pursuant to false certifications are false.

As the Second Circuit recognized in *Mikes v. Strauss*, 274 F.3d 687 (2d Cir. 2001), specific federal programs can condition payments on compliance with a statute, by contracts or by regulations, beyond what the statute itself may require across all the relevant federal programs. *Id.* at 697 (noting that "a false claim may take many forms," including if the claim is for "goods or services ... provided in violation of contract terms, specification, statute, or regulation") (citing to S. Rep. No. 99-345, at 9). Here, the Government alleges that, to obtain reimbursement from Medicare and Medicaid, pharmacies had to expressly certify or represent their compliance with the AKS. For example, Medicare Part B, which paid for Myfortic shipments, required a pharmacy to certify that it "understand[s] that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with ... the Federal anti-kickback statute ...." US Am. Compl. at ¶ 23.

The Part B certification "was a 'prerequisite [] and the *sine qua non* of federal funding;" thus, when a pharmacy makes that certification, but then submits claims to Part B in connection with an "underlying [kickback] transaction," this renders both the certification and those claims false. *U.S. ex rel. Osheroff v. Tenet Healthcare Corp.*, 09-22253-CIV, 2013 WL 1289260 at *4 (S.D. Fla. Mar. 27, 2013) (internal quotation marks omitted); *see generally Parikh*, 977 F. Supp. 2d at 664 n.3 (agreeing with "numerous courts [that] have held ... allegations referring to [the Part B certification] are sufficient to plead certification as required for FCA liability"). Medicare

Part D, which paid for Exjade shipments, and Medicaid also required pharmacies to certify or represent that they will comply with the AKS in order to obtain reimbursements from those programs. *See* US Am. Compl. at ¶¶ 29, 36. The pharmacies' violations of those certifications similarly rendered both their certifications and the claims submitted thereunder false.

While, as *Parikh* noted, many courts have found falsity based on express certifications like the Part B provider agreement, 977 F. Supp. 2d at 664 n.3, they did not require a showing of "but for cause" as an element of falsity. Novartis also has not proffered any reason why such a requirement should somehow be injected into this falsity standard.

POINT III

NOVARTIS'S "OVER-BREADTH" ARGUMENTS IN FACT UNDERSCORE WHY A "BUT FOR CAUSE" REQUIREMENT SHOULD NOT BE INJECTED INTO THE FALSITY STANDARD

Finally, Novartis wrongly claims the Government's theory provides "no limit on the taint." NPC Br. at 21. As discussed above, the Government is not postulating a "limitless" theory of taint; instead, under the Government's theory, falsity turns on whether the claim can be linked to the kickback violation. *See supra* at 9-13. Indeed, an analysis of Novartis's hypotheticals shows that the Government's theory does not lead to, as Novartis suggests, a "parade of horrible."

Novartis's first hypothetical involves a semantic sleight of hand – Novartis again conflates a "prescription" issued by a doctor with the actual drug shipment dispensed by a pharmacist. *See supra* at 4. To be clear, the Government is seeking recovery in this case for shipments dispensed by pharmacies that agreed to take kickbacks from Novartis, not "prescriptions" issued by doctors. In any event, under the Government's theory, a prescription is not false if it was not issued in connection with the kickback violation.

Novartis's second and third hypotheticals both are untethered to the Government's theory

in this case, which is based on claims for two specific drugs dispensed by pharmacies during the course of their kickback relationships with Novartis. First, those hypotheticals fail to state what certifications (if any) were made to Medicare and/or Medicaid in the hypothesized cases. As discussed above, this is highly relevant to whether claims submitted pursuant to the certifications are false. *See supra* at 16-18.

Novartis likewise fails to specify the basic terms of the kickback arrangements, which also are important to discern whether claims are linked to the kickbacks. For example, under the Government's theory, whether a Myfortic claim from a pharmacy that received a kickback from Novartis "in year one" is false turns on, in part, what Novartis sought in return for that kickback — if Novartis gave the pharmacy a lump sum kickback payment "in year one" to induce the pharmacy to promote Myfortic for multiple years, then the Myfortic claims generated by that pharmacy beyond the first year may be false. Likewise, whether a kickback scheme taints one drug or a group of drugs similarly depends on what the nature of the kickback scheme — if the drug-maker offered the pharmacy kickbacks under the guise of a "research grant" for a single drug to induce the pharmacy to recommend or purchase several drugs, then the claims for all those drugs may be false.

Ultimately, those scenarios underscore the point that falsity in FCA cases involving kickbacks should not be determined under a rigid, "but for cause" requirement, but instead should focus on whether a link exists between the claim and the specific AKS violation.[8]

[8] Novartis also suggests that adding a "but for cause" requirement is mandated because it views the Government's theory in this case to be "a dramatic departure from prior enforcement actions." NPC Br. at 18-20. Novartis's perception of the Government's enforcement choices is irrelevant and, in any event, is simply inaccurate. First, it is beyond cavil that the language of the applicable statutes and relevant precedents define the scope of Novartis's liability for offering kickbacks to pharmacies, not which cases the Government decides to (or not to) bring. Indeed, the Government's enforcement decisions reflect exercise of prosecutorial discretion that is of no moment here. *Cf. Heckler v. Chaney*, 470 U.S. 821, 831 (1985) ("This Court has recognized on

CONCLUSION

For the reasons set forth above, the Court should deny Novartis's motion to dismiss in its entirety. Specifically, the Government has sufficiently pled the falsity of the Myfortic claims cited in the amended complaint because the Myfortic kickback scheme tainted those claims and because those claims were submitted pursuant to false express certifications in the pharmacies' Part B provider agreements. Likewise, the Government has sufficiently pled the falsity of the Exjade claims cited in the amended complaint because, first, those claims are false because the Exjade kickback scheme tainted those claims and because those claims were submitted pursuant to BioScrip's false representations in its Part D subcontracts and Medicaid agreements.

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Respectfully submitted,

PREET BHAHARA
United States Attorney
Southern District of New York

By: /s/ Li Yu
LI YU
REBECCA C. MARTIN
ROBERT WILLIAM YALEN
TARA M. LaMORTE
Assistant United States Attorneys
86 Chambers Street, 3rd Floor
New York, NY, 10007
Tel.: (212) 637-2734/2714/2722/2746
Fax: (212) 637-2686/2702

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several occasions over many years that an agency's decision not to prosecute or enforce, whether through civil or criminal process, is a decision generally committed to an agency's absolute discretion"). In any event, Novartis's list leaves out cases where the Government has successfully asserted FCA claims based on kickback relationships between pharmacies and drug-makers, *see, e.g.*, *Pharm. Indu. Avg. Wholesale Price Litig.*, 491 F. Supp. 2d 12; *Lisitza*, 765 F. Supp. 2d 112, and resolutions in other FCA matters that did not proceed to litigation.